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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,497

06/17/2005

Hui Dong

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07/05/2006

Daniel J. Hudak
Hudak Shunk & Farine Co.
Suite 307
2020 Front Street,
Cuyahoga Falls, OH 44221

EXAMINER

MCCORMICK, MELANIE LEE

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/539,497	Applicant(s) DONG, HUI	
	Examiner Melenie McCormick	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>06/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group I (claims 1-6) in the reply filed on June 7, 2006 is acknowledged.

Claims 1-6 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 recite the limitation "The composition" in line 1. Claim 3 recites the limitation "the Absorptive Resin" in line 5. There is insufficient antecedent basis for these limitations in the claims.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Overall, the claim language is unclear and confusing for reasons too numerous to individually indicate. Examples of unclear claim language are presented below.

In claim 1, the use of the plural term "extracts" renders the claim confusing and indefinite, as it is not clear if applicant is referring to more than one extract. To more clearly describe the invention, it is suggested that claim 1 be amended to recite, for example, "A composition comprising an Epimedium extract, wherein the extract comprises...". In claim 2, it is unclear if the terms "flavones" and "polysaccharides" are referring to the flavones and polysaccharides of claim 1. To more clearly describe what is being claimed, it is suggested that the terms "the flavones" and "the polysaccharides"

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replace the terms "flavones" and "polysaccharides". In claim 3, the phrase "adding onto the Absorptive Resin (D₁₀₁ or D₁₄₀) Column" is rendered vague and indefinite, as it is unclear what is being added onto the absorptive resin column. In claims 3 and 5, the phrase "standing still" rendered vague and indefinite, as it is not clear what is standing still.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The claims are drawn to a composition of *Epimedium* extracts comprising flavones and polysaccharides in ratios varied from 2:8 to 8:2 by weight which are used in treatment of prostatic hyperplasia and wherein the total flavones of the extracts are in

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the range of 20-90%, and the molecular weights of the polysaccharides vary from 1,000 to 700,000 Daltons.

Chen et al. (US 6,123,944) disclose an icariin-containing preparation obtained from the aerial parts of plants of the *Epimedium* genus (see e.g. col 1, lines 30-32). Chen et al. further disclose that the preparation contains about 15% to about 95% icariin by weight and about 5% to about 80% of non-icariin flavones by weight (see e.g. col 1, lines 32-36). These values overlap with the range of icariin and total flavones of the extracts instantly claimed. The extract taught by Chen et al. would inherently contain polysaccharides of the molecular weights instantly claimed, as it is not indicated by Chen et al. that the polysaccharides have been removed. Consequently, the claimed composition of *Epimedium* extract appears to be anticipated by the reference.

In the alternative, even if the claimed extract composition is not identical to the referenced extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced extract composition is likely to inherently possess the same characteristics of the claimed extract composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed extract composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

With respect to the art rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so, to what extent, from that of the

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discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6,123,944) and Mitsuhashi et al. (US 4,501,736).

A composition of *Epimedium* extracts comprising flavones (including icariin) and polysaccharides and a method of *Epimedium* herb extraction is claimed.

Chen et al. beneficially teach an *Epimedium* extract which comprises flavones and polysaccharides, and is relied upon for the reasons set forth above. Chen et al. further beneficially teach a method of *Epimedium* extraction (see e.g. claim 1). The method of extraction beneficially taught by Chen et al. comprises the steps of extracting the *Epimedium* plant with water, loading the *Epimedium* extract onto hydrophobic column, washing the column with a polar solvent and then washing with a second, less polar solvent, and removing the solvent to yield a dry product (see e.g. claim 1). Chen et al. further beneficially teach that the icariin containing solvent obtained in after the second elution can be added to another column and eluted, dried, and redissolved (see

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e.g. claim 3). Chen et al. beneficially teach that the method disclosed is used to form an icariin-standardized composition, such as a pharmaceutical composition or a dietary supplement (see e.g. col 2 lines 53-57). Chen et al. do not beneficially teach that the method includes the steps of adding chloroform n-butanol mixture to precipitate protein debris, removing polysaccharides below 1000 daltons by ultrafiltration, concentrating the aqueous extract to dryness and mixing the extracted Epimedium flavones and polysaccharides.

Mitsubishi et al. beneficially teach a method of extracting Epimedium with an organic solvent, filtering the resulting solution to form a filtrate, concentrating the filtrate to obtain an aqueous extract, adding the extract to a defatting solvent such as chloroform, and then performing the steps of filtering and washing and precipitating until the desired composition is obtained (see e.g. claim 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare an epimedium extract using the method instantly claimed. It would have been obvious to combine the methods beneficially taught by Chen et al. and Mitsubishi et al. to create a method which comprises the steps of extracting the epimedium with an organic solvent, recovering the solvent from a filtrate, loading this onto an absorptive resin, eluting the column with ethanol, recovering the eluent by suction filtration and evaporating the eluent, decocting the residue with water and concentrating the aqueous solution, adjusting the ethanol content, standing still, filtering to obtain crude polysaccharides, dissolving the polysaccharides in water and adding chloroform n-butanol to precipitate protein, filtering the concentrating and

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drying the extract. One of ordinary skill in the art of plant extraction would have been motivated to combine the extraction steps beneficially taught by Chen et al., in particular the step of applying the extract to an absorptive column, with the extraction steps beneficially taught by Mitsuhashi et al. in order to obtain an epimedium extract with the particular qualities instantly claimed, which are disclosed by Chen et al. The adjustment of particular conventional working conditions (e.g. the particular type of chromatography column used or the exact mixture of flavones and polysaccharides) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



CHRISTOPHER R. TATE
PRIMARY EXAMINER